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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/219,442	12/23/1998	JING-SHAN HU	PF112P2D1	4797

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HUMAN GENOME SCIENCES INC
9410 KEY WEST AVENUE
ROCKVILLE, MD 20850

EXAMINER

LANDSMAN, ROBERT S

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 08/23/2002

28

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/219,442

Applicant(s)

HU ET AL.

Examiner

Robert Landsman

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-446 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 25.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Continuation of Disposition of Claims: Claims withdrawn from consideration are 45-52, 65-72, 85-92, 105-112, 125-132, 157-164, 177-184, 197-204, 217-224, 237-244, 257-264, 277-284, 297-304, 318-325, 339-349, 359-366, 379-386, 399-406, 419-426 and 439-446.

Continuation of Disposition of Claims: Claims rejected are 33-44, 53-64, 73-84, 93-104, 113-124, 133-156, 165-176, 185-196, 205-216, 225-236, 245-256, 265-276, 285-296, 305-317, 326-338, 347-358, 367-378, 387-398, 407-418 and 427-438.

DETAILED ACTION

1. Formal Matters

- A. The Supplemental Information Disclosure Statement, filed 4/18/02, has been entered into the record. However, since Statutory Declarations are not proper subject matter for an IDS, Applicants have not submitted a Form PTO-1449.
- B. The Supplemental Information Disclosure Statement, filed 3/12/02, has been entered into the record.
- C. The Supplemental Information Disclosure Statement, filed 1/23/02, has been entered into the record. However, since Statutory Declarations are not proper subject matter for an IDS, Applicants have not submitted a Form PTO-1449.
- D. The Supplemental Information Disclosure Statement, filed 12/21/01, has been entered into the record. However, since Statutory Declarations are not proper subject matter for an IDS, Applicants have not submitted a Form PTO-1449.
- E. The Request for a Corrected Filing Receipt, filed 3/16/01, has been entered into the record.
- F. The Power of Attorney, filed 3/16/01, has been entered into the record. This Power of Attorney recognizes Michele Wales, who signed the Terminal Disclaimer, filed 7/10/00. Therefore, this Disclaimer will be entered into the record.
- G. The Response, filed 9/10/01, has been entered into the record. Therefore, the Notice of Non-Responsive Amendment of 5/24/01, has been withdrawn.
- H. Claims 33-446 are pending in the application. In Paper No. 10, dated 3/9/00, the previous Examiner withdrew claims 45-52, 65-72, 85-92, 105-112, 125-132, 157-164, 177-184, 197-204, 217-224, 237-244, 257-264, 277-284, 297-304, 318-325 and 339-349. In Paper No. 12, filed 7/18/00, Applicants added claims 347-446. However, based on the original restriction requirement, claims 359-366, 379-386, 399-406, 419-426 and 439-446 are withdrawn as being drawn to non-elected method claims. Therefore, claims 33-44, 53-64, 73-84, 93-104, 113-124, 133-156, 165-176, 185-196, 205-216, 225-236, 245-256, 265-276, 285-296, 305-317, 326-338, 347-358, 367-378, 387-398, 407-418 and 427-438 are the subject of this Office Action.
- I. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

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2. Information Disclosure Statement

A. Reference EY of Paper No. 22 has been lined through since an International Search Report is not a proper reference for an IDS.

3. Claim Rejections - 35 USC § 101 – Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

A. The rejection of all claims under the judicially created doctrine of double patenting over claims 1-60 of U.S. Patent No. 5,932,540 on page 5-6 of the Office Action dated 3/9/00, has been withdrawn since Applicants filed a Terminal Disclaimer.

B. Claims 33-44, 53-64, 73-84, 93-104, 113-124, 133-156, 165-176, 185-196, 205-216, 225-236, 245-256, 265-276, 285-296, 305-317, 326-338, 347-358, 367-378, 387-398, 407-418 and 427-438 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over at least claims 33, 34, 49, 50, 65, 66, 81, 82, 97, 98, 113, 114, 129, 130, 145, 146, 161, 162, 177, 178, 193, 194, 209, 210, 225, 226, 241, 242, 257 and 258 of copending Application No. 09/257,272. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are claiming common subject matter, as follows: the claims of the 09/257,272 application recite isolated polypeptides comprising either a mature form of SEQ ID NO:2, 4, or those of ATCC No. 75968 or 97149, a proprotein of SEQ ID NO:2, 4, or those of ATCC No. 75968 or 97149, those comprising residues 71-396, 47-396, 24-396, 1-396 and -23-396 of SEQ ID NO:2 and a fragment of at least 30 contiguous amino acids of SEQ ID NO:2, or encoded by ATCC No. 75968 or 97149. The claims of 09/257,272 recite isolated polypeptides which are at least 90% or 95% of the mature, or proprotein forms of SEQ ID NO:2, 4, ATCC No. 75968 or 97149, as well as those comprising

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residues 71-396, 47-396, 24-396, 1-396 and -23-396 of SEQ ID NO:2 and a fragment of at least 30 contiguous amino acids of SEQ ID NO:2, or encoded by ATCC No. 75968 or 97149, which encompass claims of the present invention. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

C. Claims 133-156, 165-176, 225-236, 245-256, 265-276, 285-296, 305-317, 326-338, 407-418 are provisionally rejected under the judicially created doctrine of double patenting over claims 1-24, 46-74 of copending Application No. 09/935,726. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: the claimed polypeptide comprising various fragments of SEQ ID NO:2 and 4, such as 30 contiguous amino acids. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

D. Claims 133-156, 165-176, 225-236, 245-256, 265-276, 285-296, 305-317, 326-338, 407-418 are provisionally rejected under the judicially created doctrine of double patenting over claims 10-18 of copending Application No. 09/623,725. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: the presently claimed polypeptide comprising residues 131-144, 71-396, 24-296 of SEQ ID NO:2 and fragments including those of at least 30 contiguous amino acids of ATCC 97149 reads on 95% identity to N- and C-terminal deletion mutants of SEQ ID NO:2, as claimed in the '725 application. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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E. Claims 33-44, 53-64, 73-84, 93-104, 113-124, 133-156, 165-176, 185-196, 205-216, 225-236, 245-256, 265-276, 285-296, 305-317, 326-338, 350-358, 367-378, 387-398, 407-418 and 427-438 are provisionally rejected under the judicially created doctrine of double patenting over claims 22-89 of copending Application No. 09/107,997. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: the presently claimed polypeptide comprising SEQ ID NO:2 and methods of using those proteins, including for the treatment of angiogenesis. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

F. The Examiner brings to Applicants' attention that claims 33-44, 53-64, 347-358, 367-378, 387-398, 407-418 and 427-438 may be provisionally rejected under the judicially created doctrine of double patenting over one or more claims of copending Application No. 10/060,523. Upon performing a search of claimed SEQ ID NO:4 of the present application, Application 10/060,523 was identified as containing a sequence which is 100% identical to this sequence. However, Application 10/060,523 was not available to the Examiner at the time this Office Action was written. Applicants are hereby informed that a provisional double patenting rejection may be made in a subsequent Office Action.

G. The Examiner brings to Applicants' attention that claims 33-44, 53-64, 347-358, 367-378, 387-398, 407-418 and 427-438 may be provisionally rejected under the judicially created doctrine of double patenting over one or more claims of copending Application No. 10/084,488. Upon performing a search of claimed SEQ ID NO:4 of the present application, Application 10/084,488 was identified as containing a sequence which is 100% identical to this sequence. However, Application 10/084,488 was not available to the Examiner at the time this Office Action was written. Applicants are hereby informed that a provisional double patenting rejection may be made in a subsequent Office Action.

H. The Examiner brings to Applicants' attention that claims 33-44, 53-64, 73-84, 93-104, 113-124, 133-156, 165-176, 185-196, 205-216, 225-236, 245-256, 265-276, 285-296, 305-317, 326-338, 347-358, 367-378, 387-398, 407-418 and 427-438 may be provisionally rejected under the judicially created doctrine of double patenting over one or more claims of copending Application No. 10/127,551 (see

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claims 69-79 and 83-85). Application 10/127,551 was identified as containing sequences which are 100% identical to both SEQ ID NO:2 and 4. However, no election has been made in Application 10/127,551 at this time. Applicants are hereby informed that a provisional double patenting rejection may be made in a subsequent Office Action.

I. The Examiner brings to Applicants' attention that claims 33-44, 53-64, 347-358, 367-378, 387-398, 407-418 and 427-438 may be provisionally rejected under the judicially created doctrine of double patenting over one or more claims of copending Application No. 10/120,398. Upon performing a search of fragments of claimed SEQ ID NO:2 of the present application, Application 10/120,398 was identified as containing fragments which are 100% identical to fragments of SEQ ID NO:2. However, Application 10/120,398 was not available to the Examiner at the time this Office Action was written. Applicants are hereby informed that a provisional double patenting rejection may be made in a subsequent Office Action.

J. The Examiner brings to Applicants' attention that claims 33-44, 53-64, 347-358, 367-378, 387-398, 407-418 and 427-438 may be provisionally rejected under the judicially created doctrine of double patenting over one or more claims of copending Application No. 10/120,377. Upon performing a search of fragments of claimed SEQ ID NO:2 of the present application, Application 10/120,377 was identified as containing fragments which are 100% identical to fragments of SEQ ID NO:2. However, Application 10/120,377 was not available to the Examiner at the time this Office Action was written. Applicants are hereby informed that a provisional double patenting rejection may be made in a subsequent Office Action.

K. The Examiner brings to Applicants' attention that claims 33-44, 53-64, 347-358, 367-378, 387-398, 407-418 and 427-438 may be provisionally rejected under the judicially created doctrine of double patenting over one or more claims of copending Application No. 10/120,414. Upon performing a search of fragments of claimed SEQ ID NO:2 of the present application, Application 10/120,414 was identified as containing fragments which are 100% identical to fragments of SEQ ID NO:2. However, Application 10/120,414 was not available to the Examiner at the time this Office Action was written. Applicants are hereby informed that a provisional double patenting rejection may be made in a subsequent Office Action.

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4. Claim Rejections - 35 USC § 112, first paragraph – enablement

A. Claims 73-84, 93-104, 113-124, 245-256, 285-296 and 326-338 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 3-5 of the Office Action dated 03/09/00. Applicants do disclose in the Amendment B, filed 7/10/2000, that ATCC Deposits 75698 and 97149 are maintained under the terms of the Budapest Treaty and will be made available to a patent office signatory to the Budapest Treaty. However, Applicants have not disclosed that all restrictions on the availability to the public of ATCC Deposit 97149 will be irrevocably removed upon the granting of a patent.

B. Claims 133-156, 165-176, 225-236, 245-256, 265-276, 285-296, 305-317, 326-338, 407-418 and 427-438 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO:2 and 4 and ATCC Deposit Nos. 75698 and 97149, does not reasonably provide enablement for proteins which are less than the full-length of SEQ ID NO:2, those encoded for by ATCC Deposit No. 97149, or fragments comprising “**at least 30 contiguous amino acids**” of SEQ ID NO:2 or which are encoded for by ATCC Deposit Nos. 97149.

In In re Wands, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

First, the breadth of the claims is excessive with regard to claiming all proteins which are less than the full-length of, or “at least 30 contiguous amino acids” of SEQ ID NO:2, or encoded for by ATCC No. 97149. Proteins which are smaller than the full-length protein of the invention would have one or more amino acid substitutions, deletions, insertions and/or additions to the proteins encoded for by SEQ ID NO:2 or that encoded for by ATCC No. 97149. Applicants provide no guidance or working examples of proteins which are smaller than SEQ ID NO:2, or that encoded for by ATCC Deposit No. 97149. Applicants provide no guidance or working examples of the functions of these protein fragments are, or what amino acids can be altered (added, substituted, or deleted) in order to maintain the desired activity of these fragments. Furthermore, it is not predictable to one of ordinary skill in the art what residues can be altered while still providing the desired peptide function.

In summary, the breadth of the claims is excessive with regard to Applicants claiming all proteins which are less than the full-length of, or “at least 30 contiguous amino acids” of SEQ ID NO:2, or encoded for by ATCC No. 97149. In addition, Applicants provide no guidance or working examples of how to use these fragments, or what residues are critical to retain the claimed biological function. These

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factors, along with the lack of predictability to one of ordinary skill in the art as to how to make a peptide smaller than the full-length protein which is able to retain biological activity, leads the Examiner to hold that undue experimentation is necessary to practice the invention as claimed.

6. Claim Rejections - 35 USC § 112, first paragraph – written description

A. Claims 133-156, 165-176, 225-236, 245-256, 265-276, 285-296, 305-317, 326-338, 407-418 and 427-438 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These are genus claims. Proteins which are less than the full-length of SEQ ID NO:2, those encoded for by ATCC Deposit No. 97149, or fragments comprising “**at least 30 contiguous amino acids**” of SEQ ID NO:2 or which are encoded for by ATCC Deposit Nos. 97149 would have one or more amino acid substitutions, deletions, insertions and/or additions to the protein encoded for by SEQ ID NO:2, 4, or to ATCC No. 75698 and 97149.

The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Although these types of changes are routinely done in the art, the specification and claims do not provide any guidance as to what changes should be made. Structural features that could distinguish compounds in the genus from others in the nucleic acid or protein class are missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, SEQ ID NO:2, or ATCC No. 97149 alone are insufficient to describe the genus. One of skill in the art would reasonable conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus at the time the invention was made.

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B. Claims 33-44, 53-64, 73-84, 93-104, 347-358 and 367-378 recite a "mature form of a polypeptide." Claims 65-96, 129-160 recite a "proprotein form of a polypeptide." However, the instant specification fails to describe that portion of a protein which is the "mature" portion, or what constitutes a "proprotein." Applicant is claiming a very specific species which is not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The structure of a "mature form of a polypeptide" cannot be predicted on the basis of the amino acid sequence of the entire protein since the protein may be proteolytically cleaved in vivo, as well as being differentially processed based on which in tissue the protein is expressed. The claims are directed to a species of protein, the structure of which cannot be determined or predicted from full-length amino acid sequence and the specification does not evidence isolation or conception of the structure of the "mature form of a polypeptide," or the "preprotein form." Therefore, the specification does not provide an adequate written description of a mature protein, or preprotein form and thus the claimed invention, to the extent that it reads upon mature protein or proprotein was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
August 20, 2002

